

### REMARKS

Initially, Applicants thank the Examiner for acknowledging entry and consideration of the documents cited in the Information Disclosure Statements submitted December 2, 2004, and May 11, 2005.

Claims 36-43, 45-47, 49, 51, 52, and 54-68 are all the claims pending in the present application. Claim 40 has been amended to recite proper antecedent basis; no new matter has been added. Applicants thank the Examiner for acknowledging that claims 37-41 are directed to allowable subject matter.

Claims 36, 42, 43, 61, and 64 stand rejected under 35 U.S.C. § 102(a) as anticipated by an article (1998 AJR 170:593-597) to Eckstein et al. (Eckstein). Claims 49, 51, and 52 stand rejected under 35 U.S.C. § 102(b) as anticipated by United States Patent (USP) 5,320,102 to Paul et al. (Paul). Claims 36, 42, 43, 45-47, and 61-68 stand rejected under 35 U.S.C. § 102(e) as anticipated by USP 6,560,476 to Pelletier et al. (Pelletier). Claims 57-60 stand rejected under 35 U.S.C. § 102(a) as anticipated by a newly-asserted article (Investigative Radiology, Vol. 33, No. 5) to Kshirsagar et al. (Kshirsagar). Claims 45-47 and 65-68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein in view of USP 5,427,099 to Adams (Adams). Claims 54-56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Paul in view of Adams. Claims 62 and 63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein. Applicants respectfully traverse the prior art rejections and request reconsideration and allowance of all the pending claims in view of the following remarks.

Aspects of the present invention are generally directed to assessing the condition of a joint of a subject, and to the use of such an assessment as an aid in preventing additional damage to the joint or in facilitating treatment of damaged or diseased cartilage in the joint.

Independent claim 36 recites, among other things, elements directed to "determining the change in . . . the cartilage" over time and "converting [an electronically generated] image to a degeneration pattern." Independent claim 45 recites a method of assessing change in "a region of cartilage comprising normal and diseased cartilage" that includes use of external markers placed on the skin. Independent claim 49 recites an element directed to "mapping the amounts of [a] biochemical component in three dimensions" and an element directed to "identifying the

areas having altered amounts” of the biochemical component “thereby making a three-dimensional map of joint cartilage.” Independent claim 57 recites a method having utility in estimating cartilage change by, among other things, “identifying a region of a cartilage defect or diseased cartilage” within a defined three-dimensional object coordinate system.

The Examiner has relied upon Adams, Eckstein, Paul, and Pelletier as grounds for previous rejections; the Kshirsagar article is newly-asserted. As set forth in detail below, the asserted references are more deficient than the Examiner acknowledges, and the rejections are therefore improper.

### Rejections Under 35 U.S.C. § 102

To anticipate a pending claim under any of the various subsections of 35 U.S.C. § 102, an asserted reference must teach every element recited in the claim. *See* MPEP § 706.02. (“the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.”). As set forth in detail below, the references relied upon for the rejections under 35 U.S.C. § 102 fail to teach every element recited in the pending claims.

### Eckstein

Claims 36, 42, 43, 61, and 64 stand rejected under 35 U.S.C. § 102(a) as anticipated by Eckstein. The Eckstein article, as the title suggests, describes a study on evaluating “in vivo reproducibility of volume and thickness measurements from replicated data sets.” *See* Objective, p. 593. According to the authors, such an “investigation is required for evaluating *the potential* of MR imaging to effectively discriminate between individuals . . . and *to reliably monitor changes* in cartilage” over time. Page 595, column 1. Eckstein neither specifically teaches nor even suggests an operative system and method capable of “determining the change in thickness or volume of the cartilage” as the Examiner has stated. Eckstein arguably postulated that such a system and method might be possible at some point in the future, but that is not an enabling disclosure. Eckstein only actually teaches interscan reproducibility of measurements taken during replicated acquisitions, *i.e.*, Eckstein expected the volume measurements to be *the same*, or *reproducible*. *See, e.g.*: Page 595, column 1; Page 596, caption for Fig. 3.

Further, as Applicants have previously noted, the Eckstein article studied “volunteers who had no musculoskeletal disorders or internal derangements of the knee.” Page 594, column 1. Accordingly, Eckstein fails to teach or to suggest “converting [an] image to a degeneration pattern” as recited in claim 36. This deficiency is not surprising because Eckstein’s analysis is admittedly only appropriate “for healthy cartilage”; Eckstein’s approach is unproven “in joints with moderate and severe osteoarthritis” and in “cases of cartilage damage.” Page 596, column 1.

The portion of the Eckstein article that the Examiner has cited as teaching a “degeneration pattern” does not, in fact, address degeneration at all. At page 594, column 2, the Eckstein article discusses generating three-dimensional images of reconstructed joint surfaces. The images display an indication of thickness distribution. In that regard, Applicants note that the fair teachings of Eckstein are relevant, if at all, only to determining the thickness of cartilage at a discrete moment in time. Claim 36 recites not only “converting” an image to a “degeneration pattern” but also “determining the change in thickness” over time. Eckstein teaches nothing of the sort.

As noted above, Eckstein does not contemplate methods that are useful for degenerated cartilage; consequently, Eckstein does not teach the subject matter described and claimed in the present application. In particular, Eckstein fails to teach or to suggest at least the “converting” and the “determining the change” elements recited with particularity in claim 36.

At least for the reasons articulated above, the Eckstein reference is insufficient to anticipate claims 36, 42, 43, 61, and 64, and the rejection under 35 U.S.C. § 102(a) is improper.

#### **Paul**

Claims 49, 51, and 52 stand rejected under 35 U.S.C. § 102(b) as anticipated by Paul. At page 3 of the Office Action, the Examiner has cited column 4, lines 31-34, and column 5, lines 28-32, of Paul as teaching “making a three-dimensional map of joint cartilage.” The portions of Paul cited by the Examiner are related to MRI imaging techniques; the cited passages neither teach nor suggest “making a three-dimensional map” as recited in claim 49.

In particular, claim 49 recites “determining the areas of abnormal joint cartilage by identifying the areas having altered amounts of the biochemical component present, thereby

making a three-dimensional map of joint cartilage.” While Paul teaches quantifying MRI signal intensities to analyze proteoglycan distribution across cartilage depth (*i.e.*, in *two dimensions*), the reference does not teach “mapping the amounts of the biochemical component in three dimensions” as the Examiner has stated. Paul provides only two-dimensional data plots (*see* FIGS. 5-10 and 12(a) and 12(b) through 18(a) and 18(b)), and does not teach that such data may have utility in “making a three-dimensional map of joint cartilage.”

Addressing two-dimensional proteoglycan distribution profiles exclusively, the Paul patent fails to teach or to suggest at least the “mapping” and “making” elements recited in claim 49. Accordingly, the Paul reference is insufficient to anticipate claims 49, 51, and 52, and the rejection under 35 U.S.C. § 102(b) is improper.

#### Pelletier

Claims 36, 42, 43, 45-47, and 61-68 stand rejected under 35 U.S.C. § 102(e) as anticipated by Pelletier. As Applicants have already pointed out on the record, the earliest date to which the Pelletier patent is arguably entitled under 35 U.S.C. § 102(e) is November 1, 1999. The pending application claims priority from the December 16, 1998, filing date of a provisional application Serial No. 60/112,989. Accordingly, the Pelletier patent is not a proper reference at least with respect to pending claims 45-47 and 65-68. The rejection of these claims under 35 U.S.C. § 102(e) is improper for this reason alone.

The Examiner has failed to establish that the Pelletier patent teaches every element recited in pending independent claim 36 in any event. In particular, claim 36 recites, among other things, the following elements: “electronically transferring an electronically generated image comprising the cartilage from a transferring device to a receiving device located distant from the transferring device,” “receiving the transferred image at the distant location,” and “converting the transferred image to a degeneration pattern.”

The Examiner has cited the text at column 14, line 13, through column 15, line 23, of Pelletier as teaching these features. This portion of the Pelletier patent only addresses MRI techniques, however, and neither teaches nor suggests the “transferring,” “receiving,” and “converting the transferred image” operations recited in claim 36. While Pelletier teaches “difference mapping” techniques that compare data on cartilage structure acquired at different times (column 15, lines 19-23), the reference is deficient at least to the extent that it does not

teach the foregoing elements recited in method claim 36. Accordingly, the Pelletier patent is insufficient to anticipate claims 36, 42, 43, and 61-64.

At least for the reasons set forth above, Applicants submit that the rejection of claims 36, 42, 43, 45-47, and 61-68 under 35 U.S.C. § 102(e) is improper, and respectfully request that the rejection be withdrawn.

#### **Kshirsagar**

Claims 57-60 stand rejected under 35 U.S.C. § 102(a) as anticipated by Kshirsagar. The Examiner has cited portions of the Kshirsagar article without mapping specific quotations from the reference to specific claim elements; accordingly, it is difficult to divine exactly how the Examiner is reading claim 57 on the cited text for the reasons set forth below.

Kshirsagar teaches “defining a cuboid plug of cartilage” at page 294, column 2, which the Examiner appears to equate with the “volume of interest” recited in claim 57. Additionally, the Examiner has identified Table 1 on page 295 of Kshirsagar as teaching measurement of differences in cartilage volume over time. However, the system described in the reference merely measures overall cartilage volume within a particular volume of interest, and does not compute differences in overall cartilage volume over time. In rejecting claim 57, the Examiner has failed to address the claim language that is relevant to this difference measurement.

Claim 57 recites, among other things, an element directed to “measuring any differences in cartilage within the volume of interest between timepoints [].” The Kshirsagar reference does not teach this element. On the contrary, Kshirsagar’s cuboid blocks are “cut from the 3-D dataset” for interpolation and additional image processing. Page 295, column 1, lines 11-18. Kshirsagar’s repeated measurements reflected in Table 1 are not employed to measure differences over time, but rather to evaluate interpolation methods operative to estimate total cartilage volume at a particular point in time. Page 295, column 1, lines 1-15. As with the Eckstein article discussed above, the focus of Kshirsagar is to determine the reproducibility of measurements using image analysis techniques (Page 290, column 2, lines 5-14), and not to identify differences in volume associated with cartilage degeneration.

For at least the foregoing reasons, Applicants submit that the Kshirsagar article is insufficient to anticipate claims 57-60, and that the rejection under 35 U.S.C. § 102(a) is improper.

### Rejections Under 35 U.S.C. § 103

In order to establish a *prima facie* case of obviousness, the Examiner must at least: identify “some suggestion or motivation . . . to modify the reference or to combine reference teachings,” and establish “a reasonable expectation” that the modification or the combination would be successful. Both the motivation to modify (or to combine) and the expectation of success must be found in the prior art. Additionally, as a threshold issue, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *See* MPEP § 706.02(j). At least for the reasons set forth below, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Claims 45-47 and 65-68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein in view of Adams, and claims 54-56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Paul in view of Adams. Adams fails to supply the deficiencies of Eckstein and Paul articulated above; as a consequence, the various combinations of references, even if proper, fail to “teach or suggest all the claim limitations” as required for a proper obviousness determination.

At page 5 of the Office Action, the Examiner has cited Adams as disclosing “a marker for use with an MRI to be placed on the skin of an area of interest,” a feature admittedly lacking in both Eckstein and Paul. Further, the Examiner acknowledged that the combination of Eckstein and Adams “fails to disclose determining the width or area of cartilage or determining the change in width or area.” Applicants agree.

Additionally, Applicants reiterate a shortcoming of the Eckstein system that the Examiner continues to ignore: Eckstein’s system does not work with diseased cartilage. Eckstein’s approach is unproven “in joints with moderate and severe osteoarthritis” and in “cases of cartilage damage.” Page 596, column 1. The “region of cartilage” recited in claim 45, on the other hand, includes both “normal and diseased cartilage.”

In order for the Examiner to attempt to apply Eckstein's healthy tissue teaching to claims directed to damaged tissue, the Examiner has to apply an "obvious to try" standard, which is an improper standard for determining obviousness. *In re Geiger*, 815 F.2d 676 (Fed. Cir. 1987).

The combination of Eckstein and Adams fails to teach every element recited in independent claim 45, and the rejection of claims 45-47 and 65-68 under 35 U.S.C. § 103(a) is therefore improper.

Similarly, the Adams reference does not supply the deficiencies of Paul. In particular, Paul does not teach mapping amounts of biochemical components in three dimensions as set forth above; the Examiner's statement at the top of page 6 of the Office Action (that Paul "discloses an MRI technique to create a three-dimensional image") is misplaced because it ignores elements recited in independent claim 49. The features described above with specific reference to the Paul patent are not provided by the external markers taught in Adams.

The combination of Paul and Adams fails to teach at least the "mapping" and "making" elements recited in independent claim 49, and the rejection of claims 54-56 under 35 U.S.C. § 103(a) is therefore improper.

Claims 62 and 63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein. Again, the Eckstein article fails to teach every element recited in the pending claims. At least for the reasons articulated above with specific reference to claim 36, the fair teachings of Eckstein are insufficient to render obvious claims 62 and 63. Applicants submit that the rejection under 35 U.S.C. § 103(a) is improper.

**CONCLUSION**

At least for the reasons set forth above, Applicants submit that the present application is in condition for allowance. Early notification thereof is requested.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

The Office is hereby authorized to charge any fees, or to credit any overpayments, to Deposit Account No. 11-0600.

Respectfully submitted,

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